VA Research & Development

October 2002

New Initiatives:
Meeting Veterans' Needs

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October 2002

Department of Veterans Affairs

Veterans Health Administration

Office of Research and Development

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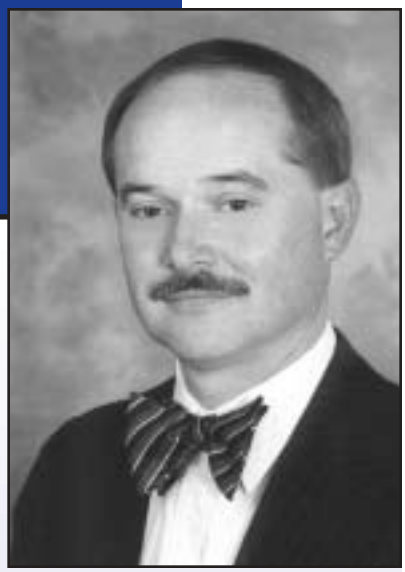
VA Research & Development

Improving health care for veterans and the nation



James F. Burris, M.D.
Acting Chief Research and Development Officer

The Office of Research and Development is proud of its role in VA's health care mission, focusing on the patient's well-being before, during and after treatment. The research enterprise supports that effort by seeking innovative solutions to medical challenges that affect veterans and non-veterans alike.

The new initiatives described in this publication advance this mission — by addressing developing issues or by approaching familiar issues in new ways.

The Cooperative Studies Program (CSP), one of the most important large-scale clinical trial programs in the world, evaluates the effectiveness of new or unproven therapies that may benefit veterans as well as the general population. CSP includes four coordinating centers, a clinical research pharmacy, and three epidemiological research and information centers.

The Health Services Research and Development Service (HSR&D) examines the organization, financing and management of health care and their effects on delivery, quality, cost, access and outcomes. Led by John Demakis, M.D., HSR&D furthers high-quality health care research through its network of key programs – including its 13 centers of excellence.

The Medical Research Service (MRS) expands our knowledge of fundamental biological processes through studies of the cause, development and treatment of diseases. Led by Paul Hoffman, M.D., MRS develops better treatments through basic and clinical research. In addition to the large number of investigator-initiated projects, MRS supports centers of excellence where researchers study AIDS and HIV, alcohol, diabetes, environmental hazards, and schizophrenia.

The Rehabilitation Research and Development Service (RR&D) is led by Mindy Aisen, M.D. The program seeks to maximize independence, minimize disability, and restore function in veterans disabled by trauma or disease. Studies funded through RR&D generally build on basic discoveries made through bench research. In addition to funding individual studies throughout the VA system, the program has 12 centers of excellence focused on spinal cord injury/dysfunction, neurologic conditions (stroke, degenerative disorders), limb loss, vision and/or hearing loss, and disabilities associated with aging.

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DEPARTMENT OF VETERANS AFFAIRS
UNITED STATES OF AMERICA

Medical Research Service

Medical Research Service (MRS) is the largest service within the Office of Research and Development, with about 1,300 currently funded investigator-initiated projects. MRS supports high-quality biomedical research benefiting veterans' health care.

It funds and administers research focusing on the origin and cause, diagnosis, and treatment of a wide range of diseases and disorders affecting veterans. The MRS portfolio includes research on cardio-vascular disease, cancer, diabetes, AIDS, neurological disorders, mental illness, and spinal cord injury.

In addition to the large number of investigator-initiated projects, the Medical Research Service supports Centers of Excellence where researchers study:

- Schizophrenia
- AIDS & HIV
- Alcohol
- Diabetes
- Environmental Hazards

Paul Hoffman, M.D.
Director,
Medical Research Service

CURRENT INITIATIVES

Merit Review Program

The Merit Review Program is the principal mechanism for sustained funding of biomedical and behavioral research for VA scientists. Proposals, on topics of fundamental importance to veterans' health, are peer-reviewed semi-annually by 18 Merit Review subcommittees, which provide MRS with a fair and objective evaluation of the scientific and technical merit, and recommends funding levels and duration for these investigator-initiated research programs. The program is open to both clinician and non-clinician scientists, and offers research support of up to $150,000. The awards are up to five years in duration dependent upon the investigator's level of experience, and funding history. Salary support is available to non-clinician scientists.

In 2001, MRS funded over 1,100 Merit Review studies on the etiology, development, diagnosis, and treatment of virtually the full range of diseases and disorders affecting veterans.

Estimated Funding:
FY '02 $133 million
FY '03 $140 million

Career Development Program

The MRS Career Development Program provides salary and research support to a fully trained clinician who is entering, or has recently entered, a research career. The applicant, nominated by a VA medical center, proposes to develop research skills in areas of importance to the mission of VA. The junior clinician is expected to spend 75 percent of his or her time in the research setting and is paired with a senior VA investigator who provides research training. In 2001, MRS funded more than 100 career development awards.

Estimated Funding:
FY '02 $12.5 million
FY '03 $10.2 million

Merit Review Entry Program

The Merit Review Entry Program (MREP) was established in 1998 to increase opportunities for beginning investigators, both M.D. and Ph.D. to enter VA's Medical Research Program by competing for a separate pool of funding. MREP support is for non-renewable, mentored, three-year awards limited to $50,000 per year plus a maximum of $15,000 for equipment. For non-clinician scientists, salary support is also available. In fiscal year 2001, MRS funded 120 MREP awards.

Estimated Funding:
FY '02 $8.5 million
FY '03 $8.4 million

Research Enhancement Award Program

Medical Research Service established the Research Enhancement Award Program (REAP) in 1998 to promote and support groups of VA investigators studying medical areas of importance to the veteran population. The REAP enables researchers to integrate basic science and clinical research approaches to understanding and treating these conditions. The goals of REAP are to:

- Train new investigators in research areas of importance to veterans health;
- Develop new and innovative research approaches to medical problems;
- Foster collaboration among investigators working in common areas.

Twenty-six programs at 23 VA medical centers were funded under this initiative. These REAPs focus on a wide variety of medical areas of particular importance to veterans, including pulmonary disease, bone disease, Parkinson's disease, vascular disease, renal disease, disorders of the gastrointestinal system, wound healing, multiple sclerosis, hepatitis C, depression, diabetes, and prostate cancer.

Estimated Funding:
FY '02 $7.1 million
FY '03 $6.1 million

Research Training Initiative for HBCU and HSI

The Research Training Initiative for Historically Black Colleges and Universities (HBCU) and Hispanic-Serving Institutions (HSI) was established to address the health care needs of the nation's African American and Hispanic American veterans, strengthen the research skills of minority faculty scientists, and stimulate the interest of minority students in pursuing VA careers in biomedical and behavioral research. This initiative has led to research collaborations and training opportunities between VA and these minority-serving academic institutions. Faculty and students may apply for Research Training Initiative awards for the support of training and collaborative research. Applicants are strongly encouraged to pursue research on medical problems prevalent among African Americans and Hispanic Americans.

This minority program has expanded through the new Research Experience Program, which is open to all students and faculty enrolled in or employed by an HBCU, HSI, or Native American college. The purpose of the Research Experience Program is to recruit more new investigators into VA's research programs, especially from underrepresented racial or ethnic groups. The program will support the salary of undergraduate or graduate students, post-doctoral fellows or faculty members so they may conduct research at a VA medical center. The trainee's research must be related to currently VA-supported research. Support will be through a supplement to ongoing VA sponsored research that is not a salary-only or mentored research program. The research experience may be up to two years and will be overseen by the principal investigator of the research program supporting the participant. Proposals are reviewed for the suitability of the background and training of the proposed participant and the benefit to that individual's career development.

Estimated Funding:
FY '02 $1.4 million
FY '03 $1.5 million

Epidemiologic Research Initiative

In 1997, VA's Office of Research and Development announced the opportunity for investigators to submit epidemiological research proposals for review under the Medical Research Merit Review Program. The Office of Research and Development is especially interested in research on the epidemiology of chronic diseases, but epidemiological proposals may be submitted in any area of particular importance to veterans. Applications must show relevance to major veteran health-related problems, and they must also show the contribution the research project is expected to make to veterans' health care. The investigator may request funds of up to $150,000 per year for up to five years. Requests for larger studies will also be considered.

Estimated Funding:
FY '02 $3.1 million
FY '03 $3.5 million

Parkinson's Disease

Parkinson's disease is a progressive, degenerative disease that accounts for significant morbidity and mortality among veterans and the general population. In September 1997, the Office of Research and Development announced a new program combining basic studies with genetic, epidemiological, and clinical studies of the disease. This program allows VA investigators with a funded Merit Review Program to submit a second Merit Review proposal in the area of Parkinson's disease and neurodegenerative disorders. Under this program nine proposals have been funded. With the advent of the Parkinson's Disease Research, Education and Clinical Center and the establishment of three REAPs dealing with Parkinson's disease and neurodeficits, the research portfolio for Parkinson's disease has greatly expanded.

Estimated Funding:
FY '02 $1 million
FY '03 $900,000

VA/DOD Collaborative Research

This collaborative program was established to fund research in areas of mutual interest to VA and the Department of Defense (DoD). Two initiatives, "Mechanisms of Emerging Pathogens" and "Combat Casualty and Wound Repair" have been completed. Following are descriptions of the remaining initiatives.

Traumatic Brain Injury

Traumatic Brain Injury (TBI) and its consequences affect both active duty military personnel and veterans. Penetrating head injury is a major concern during military operations, while closed head injury is more common in civilian life. Although the pathophysiology of penetrating and closed injury may differ, both types can result in long-term impairment of physical, cognitive and behavioral functioning. In order to advance treatment and rehabilitation following TBI, fundamental information about the acute and long-term processes is essential.

Topics proposed in response to the TBI initiative include:

- Development of innovative, humane in vivo models for penetrating injury; primary and secondary therapeutic interventions following TBI;
- Relationships between the neurobiology and neuropsychology of acute and chronic TBI;
- Relationship between pathophysiology of TBI and the effectiveness of interventions;
- Innovative approaches to conditions resulting from TBI, such as post-traumatic epilepsy (including primary prevention strategies), cognitive deficits, and mood impairment;
- Impact of rehabilitation strategies on neural plasticity following TBI, using imaging, neurobiological and cognitive approaches.

Estimated Funding:
FY '02 $400,000
FY '03 $400,000

Physiological Foundations of Physical Performance and Combat Readiness

Developing and maintaining high levels of physical fitness are of major importance for combat readiness and for general health in the veteran population. In contrast, physical fitness is a challenge for many veterans with chronic ailments, such as heart disease, type II diabetes, stroke or spinal cord injury. This initiative solicited proposals related to physical performance of active duty military personnel, optimizing and sustaining performance for combat readiness, and maintaining fitness and health following termination of active duty. Basic and applied physiology, biomechanics and epidemiology were appropriate approaches for the studies.

Topics submitted in response include:

- Mechanistic studies relating cardiovascular function, muscle physiology and metabolism to exercise and performance;
- Gene regulation and expression related to exercise and physical training;
- Physiological correlates of body composition in relation to performance or health;
- Biomechanical factors affecting human performance, including dynamic balance and its relationship to falls;
- Exercise physiology in individuals with disabilities such as type II diabetes, spinal cord injury, congestive heart failure, or stroke;
- Epidemiology of long-term health impact of exercise and physical fitness.

Estimated Funding:
FY '02 $700,000

CENTERS OF EXCELLENCE

Research Centers for Basic Science and Clinical Studies on Alcoholism or Substance Abuse

A major problem facing many veterans is substance abuse (alcohol and/or drugs), which has wide-ranging, deleterious effects resulting from dependence and toxicity. In response to the need for research related to the cause, treatment and prevention of alcoholism, Medical Research Service solicited proposals for research centers on Alcoholism or Substance Abuse. A committee of nationally recognized experts in the fields of alcoholism or substance abuse reviewed proposals and recommended two centers for funding beginning in January 1999.

The West Haven VA Alcoholism Research Center is working to better understand the biology and genetics of alcoholism and to translate those findings into improved care of alcoholic veterans. The Omaha VAMC Research Center for Basic and Clinical Studies of Alcoholism is researching the basic mechanisms of alcoholic liver disease. Both centers enhance the larger mission of VA research by advancing the understanding and treatment of alcoholism.

Estimated Funding:
FY '02 $600,000
FY '03 $600,000

Environmental Hazards Research Centers

VA's recognizes the importance of basic science and clinical research studies of environmental hazards, particularly as such studies relate to veterans' potential exposure to chemical and biological hazards during active military duty. Consequently, Medical Research Service has been supporting research on environmental hazards since 1995 when the first of four Environmental Hazards Research Centers were funded. In 1999, MRS requested proposals for new environmental research centers for basic and clinical science studies of environmental hazards.

Following review by a committee of nationally recognized experts, two centers were recommended for funding. The Boston VA Environmental Hazards Center focuses on behavioral neurotoxicology, while the San Antonio VA Environmental Hazards Center is researching the genetics of sensitivity to oxidative damage by environmental hazards.

Estimated Funding:
FY '02 $600,000
FY '03 $600,000

AIDS Centers

VA recognizes the importance of basic science and clinical research studies of Human Immunodeficiency Virus (HIV) infection and Acquired Immunodeficiency Syndrome (AIDS), including relevant retroviruses and retroviral diseases. Consequently, MRS has been supporting research centers on HIV and AIDS since 1993. Following recompetition of new and existing centers, two centers on AIDS and HIV Infection were approved for funding through fiscal year 2006, in San Diego and San Antonio. It is anticipated that a competition for new Research Enhancement Award Programs on topics such as AIDS and chronic viral infections will be announced in fiscal year 2002.

Estimated Funding:
FY '02 $750,000
FY '03 $600,000

VA/JDF Diabetes Research Centers

VA recognizes the importance of basic science and clinical research studies of diabetes, a disease that affects the veteran population with a high incidence. Because of the complications associated with the disease, the cost to patients in terms of disability and to the medical system in terms of expense is significant. Consequently, VA's Office of Research and Development has joined with the Juvenile Diabetes Foundation (JDF) to support research studies on diabetes through the establishment of Diabetes Research Centers. Funding for the three centers currently supported through this initiative will end in 2002. The centers will not be recompeted but JDF and VA are reviewing suggested areas for future collaboration.

Estimated Funding:
FY '02 $350,000

Research Centers for Schizophrenia

Schizophrenia is a complex mental disorder that affects patients and their families over a lifetime. The long-term care of schizophrenic patients is very expensive for the VA and society in general. In order to enhance and expand the research into the etiology, pathogenesis and treatment of schizophrenia, MRS has been supporting research centers on schizophrenia since 1989.

Two centers are currently funded under this initiative. They are located at VA's Medical Centers in Denver and West Haven.

Estimated Funding:
FY '02 $600,000
FY '03 $600,000

PLANNED INITIATIVES

Research Infrastructure Program

Recognizing the importance of maintaining and improving physical and operational infrastructure, VA's Office of Research and Development has established a new infrastructure program to assist VA facilities in making necessary improvements. The Medical Research Service Shared Equipment Evaluation Program (ShEEP) is being established to consolidate and replace two current equipment review committees: the Medical Research Equipment Committee and the Animal Facility Equipment Committee.

Proposals for new and replacement research and animal facility equipment will be reviewed annually. A second component of the infrastructure program, the Research Evaluation Project, will assess the status of the research infrastructure through surveys of VA medical centers nationwide. Following this assessment, the survey teams will make recommendations for improvements to a facility's plant, research equipment, and/or the organizational structure supporting research. The Research Evaluation Project is expected to be fully implemented in 2002.

Estimated Funding:
FY '02 $5 million
FY '03 $6 million

Single-Site Clinical Trial Program

MRS plans to establish a program to review proposals for single site clinical trials. This program will operate concurrently with the Merit Review Program, but will allow an investigator to have a funded clinical trial program in addition to a regular Merit Review award.

It is important to MRS that the topic proposed by an investigator will produce a definitive answer or will lead to a larger clinical trial.

Estimated Funding:
FY '02 $500,000
FY '03 $750,000

The William S. Middleton Award: 2002

VA's highest honor for medical research investigators

Eugene C. Butcher, M.D.

VA Palo Alto Healthcare System

Dr. Butcher's scientific achievements have spanned his entire research career. Among his many original contributions to the understanding of the immune process, he has helped define the molecules and mechanisms that lymphocytes (white blood cells) use to "know" where to leave the blood, and where to go once they enter the surrounding tissues — a process called homing. As much as any scientist, Dr. Butcher has stimulated and broken new ground in understanding the molecular basis of lymphocyte homing.

Although his research is not specifically disease related, it is directly relevant to the fundamental processes of the immune response and inflammation processes of numerous diseases that affect veterans. The importance of his work and its scientific impact are easily demonstrated. VA Medical Research Service has continuously funded him since 1982, and the National Institutes of Health (NIH) has funded Dr. Butcher since 1983. In 1987 Dr. Butcher received the very prestigious NIH Merit Award, which has continued uninterrupted. He has also had 254 works published in several journals.

His accomplishments as a teacher and mentor are as impressive as his scientific accomplishments. Thirty-eight scientists have completed post-doctoral training in Dr. Butcher's laboratory; most hold academic appointments. He has trained numerous fellows, graduate, and undergraduate students and most impressively, 12 professors have spent sabbaticals with him.

Presented annually to recognize outstanding achievement in biomedical or behavioral research, the award was established in 1960 to honor Dr. William S. Middleton, a distinguished educator, physician, and scientist, who served as Chief Medical Director of VA from 1955 to 1963.

DEPARTMENT OF VETERANS AFFAIRS
UNITED STATES OF AMERICA

Cooperative Studies Program

John Feussner, M.D., M.P.H.
Chief,
Cooperative Studies Program

The Cooperative Studies Program (CSP) conducts large clinical trials at multiple VA medical centers, reaping greater benefits than can be achieved from a single-site study. CSP also conducts collaborative trials with universities and other public and private facilities in the United States and other countries.

A major objective of the CSP mission involves using clinical trial research results to establish new standards of care and improve veterans' health. The program also seeks to provide research findings that improve the efficiency of VA health care system, and enhance the health of the U.S. population as a whole.

CSP includes the following research management center organizational structure:

Four Coordinating Centers
A Clinical Research Pharmacy
Three Epidemiological Research and Information Centers

CURRENT INITIATIVES

Enhancing Quality of Informed Consent (EQUIC)

Clinical trial researchers must ensure that patients' participation in research is informed and voluntary. The EQUIC project examines various approaches of providing informed consent in clinical trials in VA's Cooperative Studies Program. Such an effort is a special responsibility of VA, given the profound trust placed in the research enterprise by veterans.

EQUIC measures the quality of informed consent using the following methods:

- Self-monitoring (a questionnaire to assess a patient's understanding of the informed consent process, self-administered to patients by study coordinators).
- Cognitive stratification (obtained by a test to assess a patient's cognitive ability, followed by a tailored informed consent process).
- Pre-recruitment video (a patient-activation video designed to prevent several common misconceptions and provide prospective research volunteers with a sense of the purpose and methods one would experience in a VA clinical research study).

Estimated Funding:
FY '02 $278,000
FY '03 $290,000

Genetic Tissue Banking in VA Clinical Research

In an effort to show that it is feasible and cost-effective to create a central facility for storing genetic tissue, this study outlines a plan for a genetic tissue databank for the Cooperative Studies Program. The DNA Bank Project includes the following components:

- A central repository for DNA and other genetic tissue specimens.
- A scientific advisory committee with expertise in the genetics and epidemiology of diseases with special importance to VA (including cardiovascular, neurologic, respiratory, psychological and other disorders).
- An ethical oversight committee of individuals with expertise in bioethics and the law, as they apply to the collection and use of genetic tissue.
- A coordinating center to administer the tissue bank, coordinate the scientific and ethical oversight committees, maintain central access to clinical study data linked to the tissue bank, and provide statistical analysis.

Estimated Funding:
FY '02 $544,000
FY '03 $560,000

The Home International Normalized Ratio Study (THINRS)

Patients with blood that clots at an elevated rate have an increased risk for death, stroke, bleeding and other adverse vascular events.

Prothrombin time (PT) tests measure the rate at which one's blood clots, and are routinely performed on patients taking medication that inhibits the body's natural clotting ability. PT can monitor both the well-being of the patient and the effectiveness of anticoagulation medication.

This trial will evaluate the clinical effectiveness of home monitoring PT devices versus standard monthly management of patients, among 3,200 veterans.

Estimated Funding:
FY '02 $4.1 million
FY '03 $2.3 million

Efficacy and Safety of Testosterone in Elderly Men (ESTEEM)

A decrease in bone mineral density and muscle strength in elderly men may be linked with lower levels of testosterone. ESTEEM, a seven-year multi-center trial, will assign 6,000 hypogonadal (hormone deficient) and osteopenic (decreased bone-density) men over 65 to either replacement doses of testosterone or placebo for an average of six years.

While there is good evidence that testosterone treatment will increase bone mineral density and lean body mass, it is not known if testosterone will decrease the incidence of fractures and improve muscle strength and power among elderly men. The trial will be conducted in collaboration with the National Institutes of Health and the National Institute on Aging.

Estimated Funding:
FY '02 $9.9 million
FY '03 $17.5 million

Randomized Clinical Trial of Cognitive Behavioral Treatment for PTSD in Women Veterans

As noted in a recent report on VA's Women's Health Project, it is important to study women veterans since they are increasingly seeking VA health care. For many women veterans, combat- and non-combat-related post-traumatic stress disorder (PTSD) is a specific health care concern associated with substantial psychosocial and functional disability.

In this 2.5-year study, 384 women veterans will receive one of two cognitive behavioral interventions:

- Prolonged Exposure consisting of 10 weekly treatment sessions that include education about and exposure to the memories of the patient's trauma.
- Present Center Therapy, consisting of a control therapy of the same duration that provides emotional support for the trauma victim.

Estimated Funding:
FY '02 $1.2 million
FY '03 $1.6 million

Open Versus Endovascular Repair (OVER) Trial for Abdominal Aortic Aneurysms

Abdominal aortic aneurysm (AAA) causes about 10,000 deaths per year in the United States. Since one in 22 veterans over the age of 50 have AAAs and one in 200 are candidates for elective surgical repair, evaluation of the most effective surgical treatment for AAA is a major clinical care issue.

Recently, the FDA approved two endovascular repair (EVR) systems for AAA that are less invasive than open surgery but more costly. EVR allows repairs to be made within the blood vessel, accessing the problem without cutting open and disturbing the immediate area. This multi-center, randomized clinical trial will compare EVR to standard surgery for safety and effectiveness. The eight-year trial will involve more than 1,200 patients.

Estimated Funding:
FY '02 $2.9 million
FY '03 $3.1 million

Selenium Vitamin E Cancer Prevention Trial (SELECT)

Selenium is an essential trace mineral in the human body. Some studies indicate mortality from cancer — including lung, colorectal, and prostate cancers — is lower among people with higher selenium blood levels or intake. This VA cooperative study will test whether administration of selenium and vitamin E, alone or in combination, will reduce the incidence of prostate cancer among healthy men aged 55 or older.

The 12-year study will involve 32,400 patients, including 6,000 veterans. It will be conducted in collaboration with the National Institutes of Health, National Cancer Institute and the Southwest Oncology Group.

Estimated Funding:
FY '02 $190,000
FY '03 $209,000

SELECT Cohort Study

The SELECT trial provides an excellent opportunity for VA to prospectively study a large cohort of racially diverse and healthy men. By collecting clinical data from medical records and patient questionnaires, researchers can analyze variables that may help explain the differing occurrence of chronic diseases over a long time.

With VA sites participating in SELECT expected to screen as many as 24,000 veterans, this provides an opportunity to recruit a parallel epidemiological cohort, minimizing the cost of screening and recruitment.

The COHORT will attempt to:

- Determine whether differences in the prevalence of common chronic conditions affecting older veterans, among African-American and white males, are explained by medical, lifestyle, dietary, or other risk factors.
- Establish a plasma and DNA bank allowing the exploration of whether racial, biochemical or genetic factors can explain variation in chronic disease rates.
- Examine the differences in resource utilization and health outcomes between racial groups in VA.

Estimated Funding:
FY '02 $327,000
FY '03 $349,000

Options in Management with Anti-Retrovirals (OPTIMA)

This trial is a study of patients with advanced HIV disease who have failed conventional HAART (Highly Active Antiretroviral Therapy) regimens including all three classes of anti-HIV drugs.

The trial will compare the effectiveness of a combination of up to four drugs to a mega-treatment of five drugs or more in prevention of death and AIDS-related events. It will also assess the possible benefits of a three-month interruption in treatment. The 3.5-year trial will enroll 1,700 patients from VA, United Kingdom and Canada.

This Tri-National Clinical Trials Collaboration represents the first study initiated as part of VA's CSP's formal clinical trials collaboration with the Medical Research Council of the U.K. and the Canadian Institutes for Health Research.

Estimated Funding:
FY '02 $2.7 million
FY '03 $2.7 million

Study of Severe Diabetes Complications

A seven-year, 1,700 patient clinical trial has begun at 20 VA medical centers to determine whether intensified blood-sugar control can prevent the major vascular complications that lead to most deaths, illnesses, and treatment costs for patients with type II diabetes. These participants will receive either standard therapy or an intensive therapy designed to maintain blood-sugar levels in a specified range.

The risk for type II diabetes increases with age, with most cases developing after age 40. More than 18 percent of Americans over age 65 and more than one-fourth of VA's patient population has type II diabetes.

Estimated Funding:
FY '02 $2 million
FY '03 $2.6 million

PLANNED INITIATIVES

Prevalence of Hepatitis C Infection in Veterans

This study seeks to estimate the prevalence of hepatitis C in a nationwide sample of veterans who receive medical care through the Department of Veterans Affairs. It will also aim to determine the association of several possible risk factors for hepatitis C (blood transfusions, intravenous drug use, tattoos, intranasal cocaine use, and multiple sex partners) in veterans.

The study will be conducted nationally at 20 VAMCs and will involve 4,000 veterans.

Estimated Funding:
FY '02 $600,000

CSP/Veteran Service Organization (VSO) Focus Groups Initiative

CSP has initiated a new policy that will routinely include VSO focus groups in review and refinement of informed consent documents for all new studies.

Using less technical language should make the documents easier to understand. At a minimum, this initiative will enhance participation of veterans in VA's clinical research process and provide an ongoing dialogue between CSP and veterans.

Estimated Funding:
FY '02 $4,500
FY '03 $5,000

Providing Better Treatments for Parkinson's Disease

Parkinson's Disease (PD) symptoms include difficult body movement, rigidity, and tremor. The disease affects about 1 million Americans who may have persistent disabling symptoms (despite treatment), or medication side effects that limit effective treatment. Deep Brain Stimulation (DBS) is a reversible neurosurgical technique that is developing rapidly as an alternative both to irreversible brain surgery and less successful medical interventions. The implanted brain stimulator acts on PD symptoms like a "pacemaker for the brain."

A growing number of studies indicate that DBS improves many symptoms of PD but it is not yet been shown that the clinical benefit is superior to that of comprehensive medical therapy, whether the clinical benefit is maintained, or which area of the brain is the best site for stimulation. This study will evaluate the efficacy of DBS to medical management and also compare the effectiveness of DBS in two different regions of the brain.

This landmark study is a new collaboration with the National Institute of Neurological Disorders and Stroke (NINDS). The six new VA Parkinson's Disease Research, Education and Clinical Centers (PADRECC), located in Philadelphia, Richmond, Houston, Los Angeles, San Francisco, and Portland, will participate in this trial.

Estimated Funding:
FY '02 $2.5 million
FY '03 $876,000

Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass

Ischemic heart disease is one of the most frequent diagnoses in VA's system. It involves the restriction of blood flow, usually by way of narrow or blocked arteries. Approximately 6,000 coronary artery bypass graft (CABG-only) procedures were performed in the VA in 1999. Throughout VA and non-VA cardiac surgery programs nationwide, myocardial revascularization is now being performed using two surgical techniques. One technique is performed with cardiopulmonary bypass (CPB) usually with the heart stopped and a pump circulating the blood (on-pump) and the other without CPB on a beating heart (off-pump).

This trial will evaluate the impact on clinical outcomes and health care costs when using an on-pump versus off-pump surgical technique for CABG-only procedures.

Estimated Funding:
FY '02 $1 million
FY '03 $1.7 million

Radial Artery Versus Saphenous Vein Grafts In Bypass Surgery

Although the radial artery was introduced as a potential option for coronary artery bypass grafting in the 1970s, enthusiasm for its use was limited compared to the standard vein grafts taken from the leg. However, the use of the radial artery graft (from the arm) has increased in recent years with the development of new vessel harvesting techniques and the introduction of a method to prevent spasms.

This study will assess the long-term outcomes among a sample of 874 patients undergoing either type of graft in a cardiac bypass procedure.

Estimated Funding:
FY '02 $500,000
FY '03 $900,000

Homocysteinemia in Kidney and End-stage Renal Disease

Homocysteine is an amino acid that may have detrimental effects on the renal and cardiovascular systems if present in elevated levels. This study will investigate whether high doses of three B vitamins (folate, B6 and B12) will lower homocysteine levels and increase survival among patients with advanced chronic renal failure or end-stage renal disease and high homocysteine levels.

A secondary objective is to determine if the vitamin combination lowers homocysteine in the blood and decreases heart attack, stroke, and amputation in the lower extremities. Researchers will also observe whether the combined dosage decreases clotting of the patient's vascular access (the point where blood is removed and returned during dialysis) among patients undergoing hemodialysis.

The six-year trial involves 36 participating VA medical centers and approximately 2,000 patients.

Estimated Funding:
FY '02 $1.8 million
FY '03 $2.6 million

Millennium Cohort Study

Frequent reports of illness following military deployment has prompted research for future conflicts to determine whether deployment-related exposures are associated with post-deployment health. The Millennium Cohort Study (MCS), a prospective study of U.S. military forces, responds to recent recommendations from the Institute of Medicine to evaluate the health of U.S. military personnel during and after military service.

The MCS will compare the health of 50,000 veterans who have been deployed to Southwest Asia, Bosnia, or Kosovo since August 1997, with 50,000 veterans who have not been deployed to these conflicts. In October 2004 and October 2007, 20,000 new military personnel will be added to the cohort. The total of 140,000 veterans will be followed until the year 2022.

Funded by the Department of Defense:
Total Funding $2.1 million

Requests For Applications

Tri-National Clinical Trials Research

CSP has issued its third solicitation for proposed clinical trials to be conducted jointly by researchers from VA and the national research agencies of the United Kingdom and Canada as part of VA's Tri-National Clinical Trials Program. Priority areas are behavioral health, prostate disease, pain management, respiratory disease, aging-related diseases, rheumatologic and musculoskeletal disorders, and Type II diabetes.

Clinical trials in health services

CSP and Health Services Research and Development have issued a joint solicitation for clinical trials to evaluate new systems or interventions designed to improve the quality and delivery of care. Priority will be given to trials proposed in improving care for patients with chronic illness; enhancing equal access and utilization of care; educating patients and families; improving patient safety; implementing evidence-based practice guidelines; and improving the quality and cost-effectiveness of substance-abuse treatment.

Clinical trials in rehabilitation

CSP and Rehabilitation Research and Development are seeking to fund clinical trials of rehabilitation interventions and models of care designed to improve the physical, psychosocial or cognitive functioning of patients with stroke, spinal cord injury, Parkinson's disease, multiple sclerosis, traumatic brain injury, and computer-assisted drafting and manufacturing (CAD/CAM) prosthetics, hearing aid outcomes, and the cost-effectiveness of rehabilitation interventions.

DEPARTMENT OF VETERANS AFFAIRS
UNITED STATES OF AMERICA

Health Services Research and Development Service

John Demakis, M.D.
Director,
Health Services Research
and Development Service

Health Services Research and Development Service (HSR&D) focuses its attention on the impact research has on hospitals, doctors and patients. Patient outcomes, quality of care, access to care, and health care costs are all priorities for HSR&D.

Additionally, the service seeks to lead advances in health care and the Veterans Health Administration, maintaining a stable bridge connecting knowledge and innovations to practice in service to veterans.

HSR&D carries out this mission through merit-reviewed research and through its key centers:

- Thirteen Centers of Excellence
- Health Economics Resource Center (HERC)
- Management Decision and Research Center (MDRC)
- VA Information Resource Center

CURRENT INITIATIVES

Investigator-Initiated Research Program

HSR&D's Investigator-Initiated Research (IIR) Program is the largest of HSR&D's programs, comprising 118 projects for fiscal year 2001. The program supports research on an array of issues important to improving health care for veterans, based on merit review sessions conducted semi-annually. Periodically, HSR&D announces special interest topics that warrant added investment. Following are HSR&D's continuing IIR initiatives.

Patient Safety

This initiative will focus on the prevention of errors and injuries in clinical care. Areas of particular interest include the prevention of adverse events; issues of patient safety in outpatient settings; evaluation of new tools or strategies for the systematic prevention of errors and injuries and/or for promoting a culture of patient safety; and organizational, systemic, structural, or exposure factors in health care settings that may affect the safety of both patients and health care workers.

Cost and Economic Research

This initiative is designed to support research on the cost and cost-effectiveness of health care interventions, and the economic evaluation of VA providers and programs.

Patient-Centered Care

Patient-centered medicine addresses needs and concerns as defined by the patient. This is in contrast with illness-centered medicine, which focuses on the technical aspects of quality health care. The goal of this initiative is to define and assess patients' expectations for VA health services and to better understand the sources of patients' expectations.

Access to Care

This initiative focuses on the outcomes of interventions that address access to VA health services as a whole as well as interventions that address access to selected VA services, and studies of interventions that could be promoted or repeated in other parts of the VA system (and possibly outside VA).

Studies may include patient-level outcomes (e.g., satisfaction with care, change in health status or functional capacity); population-level outcomes (e.g., incidence or prevalence of disease, complication or readmission rates); or system-level outcomes (e.g., quality of care, level and pattern of demand for, or utilization of services, cost or cost effectiveness of care, efficiency of care).

Alternate Delivery Models

VHA's move toward primary and managed care raises many questions about emerging new relationships among key components of the health care system, models of care, and effects on patient outcomes and on system costs and efficiencies. VHA's comprehensive range of services gives investigators a unique laboratory for studying these relationships that are undergoing rapid and dramatic change.

Examples include the relationships between care for physical and mental health conditions, the concurrent need for acute and chronic care, the transitions from one health care setting to another, the link between preventive measures and health care costs, the respective roles of primary care physicians and specialists, and the juncture of clinical and administrative concerns.

Ethnic/Cultural Variations in Care

Both inside and outside VA, race and ethnicity are associated with certain systematic differences in the amount and type of health care that individuals receive. However, the significance of treatment variations among patient and provider is not always clear. Identifying those variations that need to be corrected, and designing and implementing effective corrective action, calls for careful, explanatory studies of how ethnicity and culture do, and should, influence clinical practice.

Women's Health

Considering the increased number of female veterans, VA populations are suitable for studying a wide range of health care issues that affect both men and women. VA also provides the opportunity to focus on health care for conditions that are specific to women, more common in women, or different in women.

HSR&D supports research focused on identifying the specific health needs of female veterans, establishing a national registry, strengthening outreach, facilitating access, and improving treatment for specific diseases and conditions that affect large numbers of women veterans such as breast cancer, reproductive health, sexual abuse, mental illness, PTSD, alcohol and substance abuse.

Cross-Cutting Issues in Telemedicine

Telemedicine uses electronic information and communications technologies to provide health care when providers and patients are in different locations. HSR&D continues to support research focused on the use of telemedicine within VA's health care system. In addition to telemedicine applications that link patients to clinicians and clinicians to each other, HSR&D is also interested in telemedicine applications that link patients or family members to *information* that may influence decisions about health care utilization, or the specific services they choose.

Estimated Funding for Basic IIR and Above Solicitations

FY '02 $10.3 million
FY '03 $11 million

Other Major Investigator-Initiated Research Initiatives

Nursing Research Initiative (NRI)

The NRI encourages the development of nurse investigators to conduct independent research in high priority areas for VA. Initiated by the Under Secretary for Health and implemented by the Office for Research and Development in collaboration with the Office of Nursing Services, the NRI represents a commitment by VHA to increasing research opportunities for nurses. This announcement solicits proposals for new research pertaining to nursing and seeks to expand the pool of nurse investigators in VA.

Estimated Funding (NRI):
FY '02 $2.1 million
FY '03 $2.3 million

Quality Enhancement Research Initiative (QUERI)

The Quality Enhancement Research Initiative (QUERI) is designed to turn research discoveries and innovations, into patient care and systems improvements. QUERI not only improves individual patient care, but also systematically promotes continuous quality improvement at the national level. QUERI coordinating committees and other researchers focus on nine priority conditions: cancer, chronic heart failure, diabetes, HIV/AIDS, ischemic heart disease, mental health, spinal cord injury, stroke, and substance abuse.

Estimated Funding (QUERI)
FY '02 $5.2 million
FY '03 $6 million

QUERI Service-Directed Projects

Service-Directed Projects (SDP) improve the quality of health care for veterans and create innovations that are measurable, rapid, and sustainable. Two new projects currently support these efforts and facilitate the integration of HSR&D and the Office of Quality and Performance (OQP).

One special solicitation covers both translation of findings and the study of the translation process itself, specifically addressing the dissemination, implementation, and/or evaluation of specific, existing findings within approximately 18 months. It also addresses the growth of an evolving infrastructure that supports rapid translation at the national level. Another special solicitation by HSR&D and OQP encourages the development and submission of proposals that promote translation of existing knowledge about blood pressure control into practice.

Estimated Funding (QUERI SDP Translation)
FY '02 $4.5 million
FY '03 $4.5 million

Service-Directed Research (SDR)

SDR implements research and evaluation projects addressing system-wide or national issues identified by VA managers, scientists, Congress, and federal oversight agencies. Requests for SDR proposals may be solicited VA-wide from HSR&D Centers of excellence or from VA staff with expertise in a specific subject area. The Quality Enhancement Research Initiative also uses the SDR process. SDR QUERI projects funded in 2001 were related to foot care management of diabetics, quality of care for patients with HIV, clinical practice and outcomes of substance abuse care. A solicitation was also announced and support begun for an Initiative for Measurement Excellence**,** dedicated to serving VA researchers on measurement issues, including: searching existing scale compendiums through links on a web site; evaluating scales based on standard criteria; and developing new instruments.

Estimated Funding (including QUERI SDRs)

FY '02 $3.8 million
FY '03 $4.1 million

Career Development and Career Scientist Programs

The HSR&D Career Development (CD) and Research Career Scientist Programs were established in 1991 to support the HSR careers of clinician and non-clinician investigators in VA. Each program offers several levels of awards. The Career Development Program provides clinician investigators with salary support to enable them to pursue VA HSR interests under an experienced mentor. CD awardees are required to commit at least 75 percent of their time to HSR activities. In 2001, VA HSR&D supported 61 career development awardees.

The HSR&D Research Career Scientist Award Program is directed to senior non-clinician doctoral-level scientists. Since 1999, these awards have provided salary support as well as HSR recognition. Research Career Scientist awards are granted for five years and are renewable indefinitely, subject to merit review. HSR&D supported eight RCS awardees in 2001.

Estimated Funding

FY '02 $9.8 million
FY '03 $10.4 million

Research Experience Program

HSR&D's Research Experience Program encourages students and scientists from historically black colleges and universities, Hispanic-serving institutions and Native American-serving colleges to participate in VA's health services research endeavors. Only currently funded VA principal investigators may submit applications identifying undergraduates, graduate students, post-docs or faculty from eligible institutions to participate in this program. The program provides a unique opportunity to increase the skill mix on funded HSR studies while providing a valuable research experience for talented faculty and students associated with these important minority-serving institutions. In 2001 HSR&D funded two candidates.

Estimated Funding
FY '02 $97,000
FY '03 $137,000

HSR&D Research Enhancement Award Program (REAP)

Funds provided under this initiative are for the creation of a core program of investigators, statisticians, economists, and other social scientists to support and facilitate the development of HSR&D research projects and the training and mentoring of new investigators.

The goal is to increase HSR&D capacity by assisting VA sites that have a history of HSR&D peer-reviewed research and career development funding. Groups of investigators are eligible if they are located at VA medical centers that do not have and are not affiliated with an HSR&D Center of Excellence.

The following projects are the first to receive HSR&D REAP funding:

- Patient Safety: Safe Mobility for Frail Elderly and Persons with Disabilities
- Center for Quality Improvement Research
- Program for Interdisciplinary Research in Health Care Organization
- Information Management for Patient-Centered Treatment (IMPACT)
- Enhancing VA Health Services Research in Patient-Centered Care

Estimated Funding
FY '02 $1.5 million
FY '03 $1.9 million

Collaboration with the Office of Academic Affiliations

Since 1982, the Office of Academic Affiliations (OAA) and Health Services Research have supported approximately 130 pre-doctoral health services research trainees. Currently eight Centers of Excellence (COE) are approved by OAA to serve as pre-doctoral training sites. At the local level, these centers are responsible for solicitation and nomination of suitable pre-doctoral training program candidates. Following appropriate review by the COEs, the nominations are forwarded to OAA for review by a committee in VHA Central Office and final decision. The Chief Academic Affiliations Officer makes the final funding awards based on the committee's recommendations.

Estimated Funding
FY '02 $266,000
FY '03 $266,000

Two new Centers of Excellence selected in 2001

The HSR&D Centers of Excellence (COE) Program was established in 1983. HSR&D provided full annual core support to 11 Centers of Excellence in 2001, and selected two additional centers for awards to bring the total to 13 by 2002.

Rehabilitation Outcomes Research Center (RORC)

The newly funded Rehabilitation Outcomes Research Center for Veterans with Central Nervous System Damage, located at the North Florida/South Georgia VA Health care System, seeks to enhance access to, and the quality and efficiency of rehabilitation services. Collaborating with RR&D, the center plans to develop a national database of outcomes for individuals with stroke, develop and test outcomes related to newly emerging rehabilitation therapies and provide scientific evidence that will promote informed clinical policy in rehabilitation. Through this work, the center will help to optimize care and functional recovery for veterans with central nervous system damage.

Health Services Research Center for Health Equity Research and Promotion

HSR&D Centers of Excellence conduct research in selected priority areas and support the integration of research and practice, linking the clinical aspects of patient care and organization/management needs. Located in Pittsburgh, with an affiliate center in Philadelphia, the mission of the Center for Health Equity Research and Promotion (CHERP) is to build and sustain VHA's capacity to detect, understand, monitor, and reduce health disparities. The CHERP will develop and support research among key veterans groups, initially focusing on disparities related to race/ethnicity, socioeconomic status, and comorbid illness in patients with conditions of particular relevance to VHA (e.g., cardio-vascular disease, HIV, and alcohol and substance abuse).

Estimated Funding for New Centers
FY '02 $1.2 million
FY '03 $1.2 million

VISN Collaborative Health Services Research

This enhancement of VA health services research capacity and expertise addresses important health services research issues of broad interest to VA and to a Veterans Integrated Service Network (VISN). The project may focus on such issues as: evaluating the implementation of evidence-based clinical practice guidelines; enhancing patient access to primary, emergency room or specialty care; and evaluating innovative health care delivery systems.

All networks may obtain the services of the national HSR&D Centers of Excellence for conducting research in areas of mutual interest. However, additional capacity is needed, particularly in those networks without an established core of experienced health services researchers. Eligibility to apply under this solicitation is therefore limited to VISNs that do not currently have an HSR&D Center of Excellence.

Estimated Funding
FY '02 $792,000
FY '03 $900,000

New Partnership

The following is a new research partnership formed between HSR&D and an organization outside of Veterans Affairs.

Centers for Disease Control and Prevention

QUERI-Diabetes Mellitus is collaborating with the Centers for Disease Control and Prevention on the project, Translating Research into Action for Diabetes in VA (TRIAD-VA). This project is designed to provide a better understanding of the effectiveness of different systems and organizational features of health care delivery within VHA to improve the processes and outcomes of care for veterans with diabetes. This collaboration will allow VA to benchmark care with the private sector.

PLANNED INITIATIVES

Investigator-Initiated Research Program Priorities 2001-2004

HSR&D's Investigator-Initiated Research Program Priorities for 2001-2004 will include several new issues, including:

Bioterrorism

HSR&D is preparing a solicitation to support research related to bioterrorism. This new initiative will focus on improving the capacity of the Veteran's Health Administration (VHA) to identify, manage, and mitigate the effects of a deliberate biological attack on VHA patients and personnel. Areas of particular interest include developing workforce training modules, evaluating procedures to minimize risk of exposure, developing and evaluating guidelines and decision support systems, modeling health system response to bioterrorism, and investigating the consequences of bioterrorism on the mental health of both patients and health care workers.

Management Research

Projects will address issues of importance to VA managers and policymakers nationally, VISN-wide, within VA, within facilities and within communities. Prospective projects may explore innovative methods for predicting utilization and cost of services, thus enabling VA to better prepare for future needs. Research may focus on the relationships between VA and non-VA providers, as well as provider groups within VA. Studies may address issues of supply and demand, as well as organizational issues related to resource use and service delivery.

Rehabilitation Outcomes

Proposed studies are expected to improve the effectiveness and cost effectiveness of rehabilitation practices, both at the patient and systems levels. Research may focus on real-life applications. Investigators will explore patient outcomes — mortality, morbidity, health status, symptom relief, functional status, complications, quality of life, and patient/provider satisfaction.

Sensory Loss

Sensory loss, especially vision and hearing, as well as motor dysfunction due to stroke or injury are common problems that raise important health services research questions. Research would address sensory disorders and loss resulting from traumatic injury, military exposure, progressive disease, or aging. Such projects will likely be relevant to other targeted areas of interest such as special populations and substance abuse.

Pain Management

New research will emphasize pain management related to conditions that are prevalent among veterans and will address characteristics and/or circumstances of veterans that make pain assessment and management particularly challenging. The connection between pain management and patient safety, and possible best practices to address these issues is of paramount importance. Particular emphasis will be placed on end-of-life care and advanced disease states. Cognitive behavioral approaches to pain management may also be an important area of exploration for health services researchers.

Prostate Disease

Related projects may include the evaluation of improved prognostic tools, patient preferences and satisfaction, the management of cancer-related pain and the effectiveness of screening procedures. Studies may address psychological and social factors related to the effects of prostate cancer and its treatment. More broadly, research may be warranted on benign prostate conditions affecting the veteran population.

Minority Outcomes

Projects will address variations in outcomes for significant subgroups within the veteran population. Issues related to gender and race would be of particular importance. While ethnic and cultural variations in health care have been documented, questions remain about the causes and significance of these variations. Research would explore and explain differences between and within minority populations, and would be designed to develop interventions and policies to improve care, facilitate optimal treatment, and eliminate health care disparities.

Estimated Funding:

FY '02 $3 million
FY '03 $5 million

Merit Review Entry Program

In 2002, HSR&D plans to expand its non-clinician support to include a Merit Review Entry Program (MREP) to increase opportunities for beginning investigators to enter VA's Health Services Research Program by competing for a separate pool of funding. MREP support is for non-renewable, mentored, three-year awards limited to salary support. Awardees are expected to seek investigator-initiated research support during the award period.

Estimated Funding:
FY '02 $160,000
FY '03 $800,000

Under Secretary's Award: 2002

For outstanding achievement in health services research

Stephan Fihn, M.D.
VA Puget Sound Health Care System

Dr. Fihn's research has led to improvements in patient safety and health-care delivery for veterans throughout the nation. He heads VA's Northwest Center for Outcomes Research in Older Adults, where investigators study ways to improve the diagnosis and management of chronic diseases such as heart disease, diabetes and depression.

Among the projects he is currently leading is the Ambulatory Care Quality Improvement Project (ACQUIP), a major national study that is collecting data on the health status and utilization of care for 80,000 veterans with multiple chronic diseases. In other studies, working through VA's ground-breaking Quality Enhancement Research Initiative (QUERI), Dr. Fihn and colleagues have developed new guidelines for the diagnosis and risk stratification of patients with chronic stable angina.

Dr. Fihn has played a major role in training more than 140 physicians and scientists to conduct health-services research, and provided critical guidance to VA decision-makers on issues of health-care delivery.

Established in 1998, this award honors the highest level of achievement in VA health services research and recognizes an individual who has conducted research that significantly enhances understanding of the factors affecting the health of veterans or that has led to a major improvement in the quality of veterans' health care; has made a substantive contribution to the future by inspiring a new generation of investigators through excellence in training and mentorship; and has enhanced the visibility and reputation of VA research through national leadership.

Under Secretary's Award: 2001

For outstanding achievement in health services research

Lisa Rubenstein, M.D., M.S.P.H.
Greater Los Angeles VA Healthcare System

Dr. Rubenstein received the Under Secretary's Award for Outstanding Achievement in Health Services Research at the 2001 Health Services Research & Development Service (HSR&D) 19th Annual Meeting, held in Washington, D.C.

Dr. Rubenstein's exemplary record demonstrates her unwavering commitment to veterans and to the improvement of VA health care. Nationally recognized as a leader in the design and evaluation of systems to improve the quality of health care, Dr. Rubenstein has spearheaded the development of various innovative HSR methods, with particular attention to helping doctors and nurses work with patients on improving patient quality of life. This work has included the development of a system for telling doctors how their patients are functioning physically, psychologically, and socially. She has also developed systems for helping patients work with their primary care doctors to improve psychological well-being and recover from depression.

Dr. Rubenstein has developed reliable methods for physician and nurse experts to use in reviewing patient medical records. These methods make it possible to accurately determine the quality of care a patient received.

Established in 1998, this award honors the highest level of achievement in VA health services research and recognizes an individual who has conducted research that significantly enhances understanding of the factors affecting the health of veterans or that has led to a major improvement in the quality of veterans' health care; has made a substantive contribution to the future by inspiring a new generation of investigators through excellence in training and mentorship; and has enhanced the visibility and reputation of VA research through national leadership.

DEPARTMENT OF VETERANS AFFAIRS
UNITED STATES OF AMERICA

Rehabilitation Research and Development Service

Mindy Aisen, M.D.
Director,
Rehabilitation Research and
Development Service

VA Rehabilitation Research and Development (RR&D) Service directs programs designed to advance optimal rehabilitative health care for veterans with disabilities. The foundation for RR&D initiatives is a robust Merit Review research program, 12 RR&D centers, and a capacity-building program for recruitment of junior investigators into VA rehabilitation research programs.

Rehabilitative health care is exploding with new knowledge gained through research programs. Advances in the application of robotics and telecommunications to rehabilitation medicine offer therapeutic, as well as assistive possibilities, if appropriately developed and applied.

RR&D supports 12 Centers of Excellence where researchers study:

- Spinal cord injury and dysfunction
- Neurologic conditions such as stroke and degenerative disorders
- Limb loss
- Vision loss
- Hearing loss
- Disabilities associated with aging

CURRENT INITIATIVES

Merit Review Program

The foundation of RR&D's program is in the funding of individual studies in our areas of priority. Proposals are reviewed semi-annually by scientific panels and offer research support up to $250,000 a year for three years. Review panels include representatives of multiple rehabilitation disciplines, as well as veterans. Approximately 60 percent of the RR&D budget is used to fund individual studies submitted by investigators throughout VA's health care system.

In 2001, RR&D funded 162 studies of relevance to veterans with disabilities.

Estimated Funding:
FY '02 $22 million
FY '03 $24 million

Targeted Solicitation in Rehabilitation Science and Technology

In 2001, a special solicitation was issued under the Merit Review Program to encourage studies in the spirit of President Bush's New Freedom Initiative. Proposals targeted emerging technologies to assist persons with disabilities and/or "orphan" areas with small population bases but high relevance for veterans. Identified areas were: telerehabilitation, robotics, prosthetics, low vision, rehabilitation services, satellite and cellular technology for patient-friendly tracking systems, hearing aid studies, and innovative applications of technologies to rehabilitation. All of these will continue to be incorporated into RR&D's priority areas and it is anticipated that new proposals will continue through the established Merit Review Program.

Estimated Funding:
FY '02 $1.4 million
FY '03 $2 million

Prosthetics Research

The needs of veterans who have had an amputation are a high priority of VA research. It is not always clear which new technologies offer the best results. RR&D collaborates with VA's Prosthetics and Sensory Aids Service to determine the best prescribing practices in prosthetic delivery. A new solicitation designed to begin collecting preliminary information in this area has recently been released. Two new studies in 2002 will focus on validation of general performance and maneuverability of the recently commercialized C-Leg, an expensive but significantly improved lower limb prosthesis. Another study will examine the inter-related effects of prosthetic foot design among the various lifestyle needs of individual users, with the long-term goal of establishing objective guidelines for the prescription of currently available prosthetic feet.

In addition, RR&D has partnered with the National Center for Medical Rehabilitation Research to advance the nation's prosthetics research agenda through establishment of a "roundtable," a forum designed to bring together scientists and clinicians involved in the difficult issue of amputee management.

Estimated Funding:
FY '02 $150,000
FY '03 $250,000

Career Development Program

RR&D initiated its Career Development Program in 1997 to mentor junior investigators beginning a career in rehabilitation research. As with all VA research career development programs, the applicant is nominated by a VA medical center and works with a senior VA investigator to develop research in a priority area. In 2001 RR&D supported 16 career development awards — almost triple the number first funded in 1997.

In 2001, eight Associate Investigator awards were funded by RR&D. The Associate Investigator Program helps clinician and non-clinician scientists begin research careers. It provides a salary for postdoctoral investigators to join an ongoing Merit Review project or RR&D Center under the mentorship of a senior VA principal investigator.

Estimated Funding:
FY '02 $3.8 million
FY '03 $4 million

Research Experience Program

A corollary to the Career Development Program, the Research Experience Program is an R&D wide initiative designed to recruit new investigators from underrepresented racial and ethnic groups into VA's health care system. The program is open to all students and faculty who study or work at historically black colleges or universities, Hispanic-serving institutions and Native American-serving colleges; and supports salary for research carried out in a VA medical center. In 2001, RR&D supported one Research Experience candidate at the Salisbury VAMC working in the field of low vision.

Estimated Funding:
FY '02 $100,000
FY '03 $150,000

Special Disability Supplement

In 2001, RR&D established a program designed to encourage people with disabilities to pursue careers in science and research. The program offers salary for an investigator with a disability to work with a VA investigator on a currently funded project or program. In addition, supplemental funding is available to renovate lab space to accommodate the investigator's disability.

Estimated Funding
FY '02 $100,000
FY '03 $200,000

Information Dissemination

In addition to the regularly published *Journal of Rehabilitation Research and Development*, RR&D Service has entered into agreements to publish supplements in areas of significance in RR&D. Proceedings from VA-hosted Forum on Technologies for Successful Aging, sponsored by the White House Office of Science and Technology, were a supplement to the first issue of 2001. A planned supplement, *Pioneers of Assistive Technology*, is a review of a topic promoted by President Bush's New Freedom Initiative.

An emerging technology, functional electrical stimulation (FES), is the subject of a series of articles planned for an upcoming issue of the *Journal*. The issue will explore the place of FES in the emerging regeneration sciences. Future focus topics include multiple sclerosis and the impact of complimentary and alternative therapies on people with disabilities.

Estimated Funding:
FY '02 $50,000
FY '03 $50,000

Rehabilitation Research and Development Centers

VA RR&D centers are nationally respected resources for veterans and for the rehabilitation community at large. Research at these centers ranges from rehabilitation engineering to functional restoration. In addition to their unique areas of study, RR&D centers collectively form a national consortium aimed at solving health care questions associated with disability. In 2001, a collaborative program was initiated to encourage scientists to cross disciplines in areas of mutual interest.

These RR&D centers compete for funding every five years. The call for proposals emphasized several new areas of research, including low vision/blind rehabilitation; technologies for successful aging; evidence-based rehabilitation (rehabilitation outcomes) and physiologic techniques for validating outcomes; and neuro-rehabilitation and/or neurologic repair.

As a result, three new centers were established:

Boston - The Boston RR&D Center restores lost vision, minimizes the invasiveness of surgery, and improves delivery of ophthalmic care. Investigators' work builds on basic research in retinal prostheses, bringing together optic neural repair, nanotechnology (building electronic circuits and devices from single atoms and molecules) and low vision rehabilitation in an applied research environment. Working with the Boston VAMC eye clinic, investigators hope to enhance clinical care with new research findings. Researchers aspire to reverse age-related macular degeneration in veteran patients.

Bronx - Medical complications of spinal cord injury (SCI) are an expensive health care problem. Researchers at the Bronx VAMC have geared their studies toward providing immediately applicable, clinical solutions in this area. Primary studies will explore the use of anabolic agents to ameliorate functional, respiratory, bowel, cardiovascular, and endocrine-metabolic problems experienced by persons with SCI.

Miami - There is a mounting belief that surgical/pharmacologic therapies alone are not enough to heal damaged nervous systems. However, scientists are optimistic about rehabilitative therapies coupled with medical therapies in advancing functional restoration. The Miami VA RR&D Center is taking research findings and applying them to patient use in a joint effort with the University of Miami School of Medicine.

Approximately 25 percent of the RR&D budget is committed to core center funding. Center awards bring $750,000 per year for five years.

Estimated Funding:
FY '02 $8.2 million
FY '03 $9 million

Rehabilitation Outcomes

Like many medical specialists, rehabilitation clinicians need rigorous outcomes validation of accepted therapies. Anecdotal evidence must be replaced by statistically significant data based on large-scale trials, so RR&D has made rehabilitation outcomes research a priority component of its center program.

In addition, RR&D has partnered with VA Health Services R&D to sponsor a VA Rehabilitation Outcomes Center. As a result, a Rehabilitation Outcomes Research Center for Veterans with Central Nervous System Damage has been established at the Gainesville VAMC to enhance access to, and the quality and efficiency of rehabilitation services. The center will develop a national database of outcomes for individuals with stroke, develop and test outcomes related to newly emerging rehabilitation therapies and provide scientific evidence promoting informed clinical policy in rehabilitation.

Estimated Funding:
FY '02 $600,000
FY '03 $600,000

New Partnerships

White House Office of Science and Technology Policy

In 2001, RR&D partnered with the Office of Science and Technology Policy to host a forum on Technologies for Successful Aging. The forum brought together government agencies, not-for-profit groups, and private industry, all trying to respond to a rapidly increasing elderly population. The initiative continues to be a priority area for RR&D and other government agencies funding research focused on disability.

National Science Foundation

Both the National Science Foundation (NSF) and VA RR&D are committed to promoting the bioengineering expertise required to develop solutions sought by the disability community. The NSF Division of Bioengineering and VA RR&D are exploring a collaborative partnership to encourage junior investigators in emerging areas of science and technology.

PLANNED INITIATIVES:

Vocational Rehabilitation

VA is in a strong position to demonstrate the value of vocational rehabilitation and gather data on best practices in this area. In 2001, RR&D began collaborating with the compensated work therapy programs to devise studies that may benefit veterans, and the general population of people with disabilities. This is in line with President Bush's New Freedom Initiative. Focus will begin with the compensated work therapy programs within the psycho-social rehabilitation services of the Veterans Health Administration. If successful, RR&D hopes to expand studies to include those contained throughout VA, including those within the Veterans Benefits Administration.

Estimated Funding:
FY '02 $250,000
FY '03 $500,000

Research Enhancement Award Programs (REAPs)

There are several areas of rehabilitation research that may not be broad enough for a special center but may advance the science with a core of funding. Medical Research Service established REAPs in 1998 to promote and support groups of VA investigators studying medical areas of importance to the veteran population. These areas include vestibular therapies, speech pathology, dysphagia (a difficulty or discomfort in swallowing), and others. RR&D is planning a solicitation for REAP applications in 2002 to support research in these and other areas.

Estimated Funding:
FY '02 $125,000
FY '03 $500,000

Neuropathic Pain

Pain associated with chronic neurologic conditions occurs with one-third of spinal cord injury (SCI) patients – and a troubling consequence of the disability. It impairs both activities of daily living and quality of life. However, little evidence of appropriate treatment exists. Future solicitations and statements of priority will encourage studies in neuropathic (nervous system) pain.

Estimated Funding:
FY '02 $125,000
FY '03 $500,000

Cooperative Studies

RR&D has partnered with Cooperative Studies in a solicitation for planning requests for multi-site clinical trials of innovative rehabilitative techniques and interventions. Seven areas have been identified as highly relevant and potentially ready for trials. These include innovative motor therapy techniques, psychosocial interventions, cognitive functioning techniques, technology assessment of delivery systems such as computer-aided design and computer-aided manufacturing (CAD/CAM), pharmacological interventions adjunctive to rehabilitative therapies, hearing aid user characteristics, and rehabilitative health care interventions.

Magnuson Award: 2002

The highest honor for VA rehabilitation investigators

Dudley S. Childress, Ph.D.
VA Chicago Health Care System

Dr. Childress' groundbreaking research in prosthetics and rehabilitation technology has helped thousands of people with severe disabilities. His work includes studying the biomechanics of human walking and the design of prosthetic feet and legs.

Dr. Childress, himself a veteran of the U.S. Army, has conducted research for VA since 1981. Throughout the 1980s he worked on the development of CAD/CAM (Computer-Aided Design and Manufacture) systems to speed and improve the production of prosthetic components. His lab invented the "Squirt Shape" method for the quick and accurate production of artificial leg sockets.

Today, Dr. Childress and his graduate students are studying the biomechanics of human walking, and using this knowledge to improve the design of prosthetic feet and legs. Among their projects is the development of a relatively inexpensive prosthetic foot that may be especially helpful to amputees in poor nations.

The Paul B. Magnuson Award is presented annually to a VA RR&D Investigator who exemplifies the entrepreneurship, humanitarianism, and dedication to veterans displayed by Dr. Magnuson during his career. Serving as Chief Medical Director from 1948 to 1951, he was the architect of the current VA Health Care System, as well as VA's system of medical school affiliations. The award was established in 1998, in recognition of the importance of rehabilitation research within VA's Health Care System. It is the highest honor for VA Rehabilitation investigators.

Magnuson Award: 2001

The highest honor for VA rehabilitation investigators

P. Hunter Peckham, Ph.D.

Cleveland VAMC

Dr. Peckham's research has made it possible for some paralyzed patients to regain the use of their hands and arms. He and his collaborators have developed and implemented the procedures to provide control of grasp and release in tetraplegic subjects. This enables individuals with central nervous system disability to regain the ability to perform essential activities of daily living, such as eating and grooming.

His present efforts concern the integration of technological rehabilitation and surgical approaches to restore function. The research has provided substantial enhancement in function that is unachievable by other means.

Through the various stages of research, development, and implementation, Dr. Peckham has demonstrated versatile abilities as a basic science investigator and as a leader of a clinical research team.

The Paul B. Magnuson Award is presented annually to a VA RR&D Investigator who exemplifies the entrepreneurship, humanitarianism, and dedication to veterans displayed by Dr. Magnuson during his career. Serving as Chief Medical Director from 1948 to 1951, he was the architect of the current VA Health Care System, as well as VA's system of medical school affiliations. The award was established in 1998, in recognition of the importance of rehabilitation research within VA's Health Care System. It is the highest honor for VA Rehabilitation investigators.

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